



MedImmune

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March 29, 2010

Liz Lelacheur  
Mt State Govt  
Helena, MT 59620

Dear Liz Lelacheur:

Thank you for your recent inquiry concerning the use of Pandemic Influenza 2009 (MedImmune).

Attached are individual answers and a bibliography for each of the questions you asked. These are itemized below:

• **Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal and expiration date changes ("Field Correction Notice") [PAN09KI591]**

Your interest in Pandemic Influenza 2009 (MedImmune) is appreciated. This letter and citations are not intended to offer an opinion or advice on administering our products in a manner inconsistent with product labeling. A copy of the currently approved U.S. package insert(s) and designated (\*) literature reprints are enclosed for your review. Please feel free to call us if we can be of further assistance.

Sincerely,

Eddie Carver, PharmD  
Senior Information Specialist  
(Phone: 800-949-3789 / e-mail: [CarverE@medimmune.com](mailto:CarverE@medimmune.com))

**GENERAL PRODUCT INFORMATION:** Influenza A (H1N1) 2009 Monovalent Live, Intranasal is a live monovalent nasally-administered influenza virus vaccine with several characteristics that differ from injectable monovalent inactivated influenza vaccine (MIV). The single influenza strain contained in Influenza A (H1N1) 2009 Monovalent Live, Intranasal is *cold-adapted* in that it replicates efficiently at low temperatures such as 25°C, is *temperature-sensitive* in that its replication is reduced at higher temperatures of 37°C (for influenza B) and 39°C (for influenza A), and is *attenuated* in that it does not produce classical influenza-like illness in the ferret model of human influenza infection (*package insert*). Influenza A (H1N1) 2009 Monovalent Live, Intranasal, FluMist® and its earlier prototype formulations are commonly referred to by the CDC (Center for Disease Control & Prevention) as Live Attenuated Influenza Vaccine (LAIV).

Influenza A (H1N1) 2009 Monovalent Live, Intranasal is stored at 2-8°C/35-46°F. Influenza A (H1N1) 2009 Monovalent Live, Intranasal is concentrated by centrifugation, sterile filtered, and blended in stabilizing buffers containing monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose and phosphate. The dose volume is 0.2 mL (0.1 mL per nostril). Influenza A (H1N1) 2009 Monovalent Live, Intranasal contains the CDC recommended strain for the 2009-10 pandemic vaccine: **A/California/04/2009**.

Influenza A (H1N1) 2009 Monovalent Live, Intranasal is indicated for the active immunization of children and adults, 2-49 years of age against influenza disease caused by pandemic (H1N1) 2009 virus (*package insert*). The relative efficacy of FluMist in preventing culture-confirmed influenza in a multinational, randomized, double-blind, active-controlled (inactivated influenza vaccine) study in healthy children <5 years of age at enrollment was 44.5% (*package insert*). In a multi-center, randomized, double-blind, placebo-controlled study in healthy adults, the protection afforded by FluMist against a challenge of a single strain of wild-type influenza virus was 85% (*Treanor 2000*). Vaccination with FluMist has been demonstrated to induce both serum (IgG) and nasal secretory (IgA) antibodies (*Belshe 2000, Boyce 2000, Treanor 2000*).

FluMist has been extensively studied in people 6 weeks to 98 years of age and has a well documented safety & efficacy profile. The most common adverse reactions are runny nose or nasal congestion in all ages, fever > 100°F in children 2-6 years of age and sore throat in adults. See the enclosed prescribing information for a complete description of the CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS for Influenza A (H1N1) 2009 Monovalent Live, Intranasal. Recommendations of the **CDC Advisory Committee on Immunization Practices (CDC-ACIP)** for the use of influenza A (H1N1) 2009 monovalent vaccine were published August 28, 2009 (*CDC-ACIP 2009*). Each pre-filled Influenza A (H1N1) 2009 Monovalent Live, Intranasal sprayer must be stored at 2-8° C (35-46°F). **FOR NASAL ADMINISTRATION ONLY. DO NOT ADMINISTER PARENTERALLY.**

## **RE: Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal and expiration date changes (“Field Correction Notice”)** [PAN09KI591]

Although not specifically addressed in the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal labeling (*package insert*), we are providing the following information per your request.

On January 7, 2010, MedImmune issued a letter (“**Field Correction Notice**”) stating that twelve (12) lots of **Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal** (NDC # 66019-200-01, 66019-200-05, 66019-200-10) are affected by a shorter dating period than indicated on the label. **These lots should be used by January 15, 2010 regardless of the expiration date imprinted on the sprayer.** See Table 1 for the sprayer lot numbers, original expiration dates and the re-assigned expiration date. **After January 15, 2010, all sprayers with the lot numbers identified below should be disposed by health care providers at their individual facilities according to the standard procedures for medical waste (e.g., sharps container or biohazard container). Expired product does not need to be return to MedImmune or other third party vendor.**

**Table 1. Influenza A (H1N1) 2009 Monovalent Vaccine, Live, Intranasal Expiration Date Update**

Lot Number	Labeled expiration date	Re-Assigned
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(as printed on the sprayers)	(as printed on the sprayers)	Expiration Date
500778P	29-Jan-10	15-Jan-10
500779P	4-Feb-10	15-Jan-10
500780P	6-Feb-10	15-Jan-10
500781P	10-Feb-10	15-Jan-10
500782P	11-Feb-10	15-Jan-10
500783P	12-Feb-10	15-Jan-10
500784P	14-Feb-10	15-Jan-10
500785P	16-Feb-10	15-Jan-10
500796P	17-Feb-10	15-Jan-10
500797P	19-Feb-10	15-Jan-10
500798P	21-Feb-10	15-Jan-10
500799P	22-Feb-10	15-Jan-10

On March 19, 2010 MedImmune announced that an additional forty-seven (47) lots of **Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal** (NDC # 66019-200-05) were affected by a shorter dating period than indicated on the label. See Table 2 below for the sprayer lot numbers, original expiration dates and the re-assigned expiration date. **These lots should be used by the date indicated in the table above regardless of the expiration date imprinted on the sprayer. Expired product should be disposed by health care providers at their individual facilities according to the standard procedures for medical waste (e.g., sharps container or biohazard container) and does not need to be return to MedImmune or other third party vendor.**

**Table 2. Influenza A (H1N1) 2009 Monovalent Vaccine, Live, Intranasal Expiration Date Update**

Lot Number (as printed on the sprayers)	Labeled expiration date (as printed on the sprayers)	Re-Assigned Expiration Date
500850P	30-Mar-10	29-Mar-10
500851P	2-Apr-10	29-Mar-10
500852P	5-Apr-10	29-Mar-10

500854P	30-Mar-10	29-Mar-10
500855P	1-Apr-10	29-Mar-10
500856P	4-Apr-10	29-Mar-10
500857P	7-Apr-10	29-Mar-10
500871P	31-Mar-10	29-Mar-10
500872P	4-Apr-10	3-Apr-10
500873P	6-Apr-10	29-Mar-10
500874P	8-Apr-10	29-Mar-10
500875P	10-Apr-10	29-Mar-10
500876P	12-Apr-10	29-Mar-10
500877P	15-Apr-10	3-Apr-10
500878P	17-Apr-10	3-Apr-10
500879P	21-Apr-10	8-Apr-10
500890P	8-Apr-10	29-Mar-10
500891P	11-Apr-10	29-Mar-10
500893P	16-Apr-10	29-Mar-10
500894P	18-Apr-10	3-Apr-10
500895P	20-Apr-10	8-Apr-10
500897P	24-Apr-10	8-Apr-10
500898P	27-Apr-10	13-Apr-10
500899P	29-Apr-10	13-Apr-10
500910P	23-Apr-10	8-Apr-10
500911P	26-Apr-10	13-Apr-10
500912P	27-Apr-10	13-Apr-10
500913P	29-Apr-10	13-Apr-10
500914P	2-May-10	13-Apr-10
500833A	2-May-10	13-Apr-10

500834A	3-May-10	13-Apr-10
500835A	4-May-10	13-Apr-10
500836A	1-May-10	13-Apr-10
500837A	3-May-10	13-Apr-10
500852A	4-May-10	13-Apr-10
500853A	27-Apr-10	13-Apr-10
500854A	28-Apr-10	13-Apr-10
500855A	20-Apr-10	8-Apr-10
500856A	26-Apr-10	8-Apr-10
500873A	3-May-10	13-Apr-10
500890A	28-Apr-10	13-Apr-10
500891A	28-Apr-10	13-Apr-10
500893A	21-Apr-10	8-Apr-10
500894A	22-Apr-10	8-Apr-10
500895A	1-May-10	13-Apr-10
500898A	19-Apr-10	3-Apr-10
500899A	27-Apr-10	13-Apr-10

MedImmune is conducting this field correction with the full knowledge of the Food and Drug Administration. Should you have any questions regarding this information, please contact MedImmune at 1-877-574-5040. Should you have any medical questions please contact the MedImmune Medical Information Department at 1-877-633-4411.

A copy of the **Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal** package insert (which contains full Prescribing Information) is enclosed for your review.

**LITERATURE CITED:** (reprints enclosed as marked below with an \* - no reprints attached for FAX or e-m)

\* Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal. MedImmune, LLC. Product/prescribing information as of September 2009. [[MRM46400](#)]

*MMWR* 2009/August 21;58 (Early Release):1-8 [[MRM46128](#)]

\*Belshe RB, Gruber WC, Mendelman PM, et al. Correlates of immune protection induced by live, attenuated, cold-adapted intranasal influenza virus vaccine. *J Infect Dis.* 2000;181:1133-1137. [[MRM 19,176](#)]

\*Boyce TG, Gruber WC, Coleman-Dockery SD, et al. Mucosal immune response to trivalent live attenuated intranasal influenza vaccine in children. *Vaccine.* 2000;18:82-88. [[MRM 19,385](#)]

\*CDC-ACIP (Centers for Disease Control and Prevention/Advisory Committee on Immunization Practices). Prevention and Control of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2009/July 31;58 (RR-8):1-52 [[MRM45649](#)]

\*Treanor JJ, Kotloff K, Betts RF, et al. Evaluation of trivalent, live, cold-adapted (CAIV-T) and inactivated (TIV) influenza vaccines in prevention of virus infection and illness following challenge of adults with wild-type influenza A (H1N1), A (H3N2), and B viruses. *Vaccine.* 2000;18(9-10):899-906. [[MRM 19,170](#)]